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**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
SOUTHERN DIVISION**

17 HEMOPET,
18 Plaintiff,
19 vs.
20
21 HILL'S PET NUTRITION, INC.,
22 Defendant.

Case No. SACV12-01908 JST (JPRx)

HEMOPET'S OPENING CLAIM CONSTRUCTION BRIEF

DATE: November 18, 2013
TIME: 9:00 a.m.
PLACE: Santa Ana Courthouse,
Courtroom 10A

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1 **I. INTRODUCTION**

2 In this patent-infringement case, Plaintiff Hemopet (“Hemopet”) asserts that
3 Defendant Hill’s Pet Nutrition, Inc. (“Defendant” or “Hill’s”) infringes certain
4 claims of U.S. Patent Nos. 7,865,343 (“the ’343”); 8,060,354 (“the ’354”);
5 8,224,587 (“the ’587”), and 8,234,099 (“the ’099”) (collectively, “the Hemopet
6 patents-in-suit”). Hill’s makes, uses, sells, and offers for sale pet food products
7 developed and manufactured using Hemopet’s claimed inventions. Hill’s attempts
8 to avoid liability by proposing strained and convoluted constructions that are
9 inconsistent with the intrinsic and extrinsic evidence, that import limitations from
10 the specification and thin air, and that ignore the plain meaning of commonplace
11 words. As explained below, the Court should adopt Hemopet’s proposed
12 constructions and reject those offered by Hill’s.

13 **II. LEGAL STANDARDS**

14 Claim construction is a legal question. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 391 (1996). Claims are construed from the perspective of a
15 person of ordinary skill in the art of the field of the invention when the patent
16 application is filed. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir.
17 2005) (en banc). No “elaborate interpretation” is needed for non-technical terms
18 whose ordinary meanings are apparent. *Id.* Otherwise, courts consider the claim
19 language, the specification, prosecution history, and extrinsic evidence. *Id.* The
20 specification and claim language is “[u]sually . . . dispositive; it is the single best
21 guide to the meaning of a disputed term.” *Id.* at 1315. Prosecution history may be
22 helpful, but “often lacks the clarity of the specification and thus is less useful for
23 claim construction purposes.” *Phillips*, 415 F.3d at 1315. A party arguing surrender
24 of claim scope during prosecution must demonstrate a clear and unmistakable
25 disavowal of claim scope. *Computer Docking Station Corp. v. Dell, Inc.*, 519 F.3d
26 1366, 1374 (Fed. Cir. 2008). Extrinsic evidence should not “change the meaning of
27 the claims in derogation of the indisputable public records consisting of the claims,

1 the specification and the prosecution history.” *Phillips*, 415 F.3d. at 1319 (quotation
2 marks omitted).

3 **III. BACKGROUND OF THE CLAIMED INVENTION**

4 Hemopet is a 501(c)(3) organization which operates a greyhound rescue
5 facility, canine blood bank, and internationally active veterinary diagnostic facility
6 in Garden Grove, California. The inventor of the Hemopet patents-in-suit, Dr. W.
7 Jean Dodds, is a world-renowned veterinarian. Dr. Dodds founded Hemopet in the
8 mid-1980’s, and later assigned the patents to her organization.

9 The instructions needed for a living system to direct its activities are
10 contained within DNA and RNA. Ex. 2, Towell et al., Hill’s Pet Nutrition, Inc.,
11 Gene v. Genome: The Truth About Breed, Species, and Nutrition 2 (2008).¹ DNA
12 and RNA from all living systems are made up of the same chemical and physical
13 components called nucleotides or nucleotide bases. *Id.* A DNA sequence, for
14 example, is the particular side-by-side arrangement of nucleotide bases adenine,
15 guanine, cytosine, and thymine. *Id.* This sequence of bases spells out the exact
16 instructions required to create a particular organism with its own unique traits. *Id.*

17 The genome is an organism’s complete set of DNA or RNA. *Id.* DNA in each
18 cell is packaged into chromosomes arranged into pairs. *Id.* Humans have 46
19 chromosomes or 23 pairs; dogs have 78 chromosomes or 39 pairs; and cats have 38
20 chromosomes or 19 pairs. *Id.* Each chromosome contains many genes. Genes are
21 specific sequences of nucleotides that encode instructions on how to make proteins.
22 *Id.* The human, cat, and dog genomes are estimated to contain 20,000 to 25,000
23 genes. *Id.* Genes, however, comprise only about 2% of the human genome; the
24 remainder consists of noncoding regions, whose functions may include providing
25 chromosomal structural integrity and regulating where, when and in what quantity
26 proteins are made. *Id.* It is similar for dogs and cats.

27

¹ Unless otherwise stated, all exhibits are to the Declaration of Joseph Grinstein
28 filed concurrently with this brief.

1 Gene regulation provides additional complexity. Each gene can be thought of
2 as a book containing the information required to make a protein. *Id.* In the same
3 way that a book may be read, genes are “read” or “expressed” to produce functional
4 molecules in a cell. *Id.* In gene regulation, different genes are switched on and off
5 at different times and in different tissues, or expressed weakly or strongly, or
6 controlled in multiple ways. *Id.* Accordingly, the proteins in a cell and the amounts
7 of each can be very finely controlled throughout a cell’s life. *Id.*

8 Whether and how a gene manifests itself depends on the interaction between
9 the genome and environmental factors. *Id.* at 1. Diet is arguably one of the most
10 important environmental factors influencing health and disease. *Id.* Although genes
11 are critical for determining predilections, nutrition modifies the extent to which
12 different genes are expressed and thereby modulates whether individuals fully
13 express their genetic background. *Id.*

14 Genomics and the genomic technologies are used to elucidate the basis of the
15 interactions between diet and gene expression. *Id.* These technologies monitor the
16 activity of multiple genes simultaneously at the DNA, RNA, and protein level. *Id.*
17 For example, the term “functional genomic profile” refers to “the whole or any part
18 of the functional consequences of expression of gene sequences, including
19 production and function of mRNAs, proteins, and metabolites.” Ex. 3, Prosecution
20 History for App. Serial No. 11/469,565 (Al-Murrani), at 4688. The investigation of
21 the roles and functions of single genes does not fall within the definition of
22 genomics.

23 The field of nutrigenomics analyzes the effects of nutrients on the genome.
24 Nutrients can be thought of as dietary signals detected by cellular sensor systems
25 that influence gene and protein expression. Ex. 2 at 4. Recurring patterns of gene
26 expression, protein expression, and metabolite production in response to particular
27 nutrients or foods can be viewed as “dietary signatures” or profiles. *Id.*

1 Nutrigenomics studies these signatures to understand how nutrition influences
2 health and disease. *Id.*

3 The Hemopet patents-in-suit disclose methods and systems of using genomic
4 data and genomic map data to formulate and prepare a canine or feline diet by
5 analyzing the effects of nutrition on the genetic expression profile of a dog or cat.

6 Asserted claim 1 of the '343, for example, states:

7 1. A method of analyzing nutrition for a canine or feline animal,
8 comprising:

9 accessing at least one database that comprises first data relating
10 genetic descriptor genomic data to a physiological condition, wherein
11 the genetic descriptor genomic data is obtained from either a bodily
fluid or tissue sample;

12 accessing second data comprising the effect of nutrition on the
13 expression of the genetic descriptor genomic data;

14 analyzing, by use of a computer, the first and second data, relating the
15 effect of nutrition on the expression of the genetic descriptor genomic
16 data for the animal to the physiological condition, wherein the
17 physiological condition comprises gastrointestinal function or
immunological function of the animal; and

18 formulating a nutritional diet based on the analyzed data.

19 '343 at 23:41–24:4. And asserted claim 1 of the '587, as another example, states:

20 1. A method for determining a nutritional diet for a canine or feline
21 companion animal comprising the steps of:

22 (a) receiving first data relating the expression of at least one gene
23 from a genomic map of the animal to a physiological condition of the
24 animal,

25 (b) receiving second data comprising an effect of nutrition on the
26 expression of least one gene from the genomic map;

27 (c) determining a relationship between the first and second data
28 using a suitably programmed computer, and

1
2 (d) determining a nutritional diet for the animal based on the
3 relationship of said first and second data.

4 '587 at 25:46–26:4. In other words, “genomic data” or “genomic map data” is
5 obtained for an animal and then compared to similar data reflecting the effect of a
6 certain nutritional composition or diet on the genetic expression profile of that
7 animal. A diet can be created to address a physical characteristic by examining how
8 a specific diet affects the “genomic data” and “genomic map data” of that animal.

9 **IV. CLAIM TERMS TO BE CONSTRUED**

10 Hemopet proposes that the terms be divided into six groups that involve
11 similar concepts and support, even though they differ in scope as reflected by their
12 different language. Hemopet’s proposed constructions attempt to accurately reflect
13 these differences in scope. By contrast, Hill’s contends that different terms should
14 be assigned identical constructions. Hill’s maintains this position even when its
15 constructions directly contradict the plain language of the claims and even when the
16 plain language of the claims renders its proposed constructions non-sensical. Hill’s
17 constructions are also different from those offered by its competitor, Purina, in the
18 related litigation.

19 **A. Hill’s Boilerplate Indefiniteness Challenge Lacks Merit**

20 In addition to proposing identical constructions for terms that vary in scope,
21 Hill’s argues—erroneously and without support—that each and every disputed
22 claim term in the Hemopet patents-in-suit is indefinite under 35 U.S.C. § 112, ¶2.²

23 A claim is indefinite “only where it is not amenable to construction or is
24 insolubly ambiguous.” *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 655 F.3d

25 ² Hill’s explicitly calls out five terms as “The Indefinite Terms,” *see* Joint
26 Statement, Ex. B, at 9 (Dkt. 42), but also appears to suggest that “each term listed
27 in” the Joint Statement are indefinite earlier in its Exhibit, *see id.* at 2 n. 1. In any
28 event, none of the disputed terms are indefinite.

1 1364, 1373 (Fed. Cir. 2011) (citing *Datamize, LLC v. Plumtree Software, Inc.*, 417
 2 F.3d 1342, 1347 (Fed. Cir. 2005)). Additionally, “[a]bsolute clarity is not required
 3 to find a claim term definite,” and “a claim term may be definite even when
 4 discerning the meaning is a formidable task and the conclusion may be one over
 5 which reasonable persons will disagree.” *Id.* (citing *Source Search Tech., LLC v.*
 6 *LendingTree LLC*, 588 F.3d 1063, 1076 (Fed. Cir. 2009)).

7 Hill’s bears the burden to show indefiniteness by clear and convincing
 8 evidence. *Young v. Lumenis, Inc.*, 492 F.3d 1336, 1345 (Fed. Cir. 2007). In this
 9 case, Hill’s cannot come close to meeting its burden. As explained in more detail
 10 below, each disputed claim term in the Hemopet patents-in-suit is amenable to a
 11 construction amply supported by the evidence. In fact, for several terms, Hemopet’s
 12 proposed construction mirrors language from the specification.

13 Moreover, several courts have held that issues of indefiniteness are more
 14 properly raised in the context of summary judgment. See, e.g., *ASM Am., Inc. v.*
Genus, Inc., 2002 WL 1892200, at *15 (N.D. Cal. Aug. 15, 2002) (holding that a
 15 court “must attempt to determine what a claim means before it can determine
 16 whether claim is invalid for indefiniteness, and not . . . during the claim
 17 construction proceedings”); *Divix Golf, Inc. v. Mohr*, 2007 WL 5704046, at *28
 18 (S.D. Cal. Feb. 13, 2007) (“[A]ny argument regarding invalidity of the claim for
 19 lack enablement or indefiniteness of the claim is neither appropriate nor acceptable
 20 at the claim construction stage.”). In this case, Hill’s has not moved for summary
 21 judgment of invalidity due to indefiniteness. Given that it is Hill’s burden to
 22 establish indefiniteness, Hill’s must at this point come forward with evidence of
 23 indefiniteness before Hemopet can fully respond. Accordingly, Hill’s boilerplate
 24 claims of indefiniteness fail.

25

26 B. “Genomics” Terms

27 The first group of terms relates to the type of data that will be analyzed in
 28 order to determine an appropriate diet. In each case, Hemopet’s constructions find

1 support in the intrinsic and extrinsic evidence and recognize that different patents—
 2 through express differences in claim language—contemplate different inventions.
 3 By contrast, Hill’s proposed constructions find no support in the intrinsic or
 4 extrinsic record and fail to capture the differences in claim scope.

5 **1. “genomic data” and “genetic descriptor genomic data”**

6 Claim Term (Claim)	7 Hemopet’s Proposed Construction	8 Defendant’s Proposed Construction
9 “genomic data” 10 (’343 Patent, claim 1)	11 “data regarding the 12 genotypic profile of an 13 organism”	14 Indefinite. 15 “The entire DNA 16 sequence of an organism, not genetic information, genetic data, or gene expression data (i.e., transcription, mRNA translation, posttranslational modification, and protein gene product data).”
17 “genetic descriptor 18 genomic data” 19 (’343 Patent, Claim 1)	20 “data regarding the 21 genotypic profile of an 22 organism using elements 23 that describe gene 24 function”	25

26 Hemopet seeks construction of “genomic data” from claim 1 of the ’343.
 27 Hill’s seeks construction of “genetic descriptor genomic data” from the same claim,
 28 and while Hemopet does not think that a construction of “genetic descriptor
 genomic data” is necessary, it has proposed a construction of that term.

29 An important aspect of the ’343 and the other Hemopet patents-in-suit is
 30 data. This data, according to the ’343, relates “genomic analysis of a bodily fluid or
 31 tissue sample from an animal to a physiological condition” and “the effect of
 32 nutrition on genomic analysis.” ’343 at Abstract. The parties dispute what
 33 constitutes “genomic data” and “genetic descriptor genomic data.” Hill’s argues
 34 that these terms do not encompass several categories of data, including genetic data
 35 and gene expression data such as transcription, mRNA translation, posttranslational
 36 modification, and protein gene product data.

1 Based on the intrinsic and extrinsic evidence, however, Hill's is wrong.
2 "Genomic data" does not, as Hill's suggests, exclude data related to transcription of
3 genes, gene expression, genetic data, gene expression data, mRNA translation,
4 post-translational modification, or protein gene product data. Indeed, Hill's appears
5 to have defined "the genome," *i.e.*, the entire DNA sequence, rather than "genomic
6 data." "Genomic data" is necessarily data about all or part the genome, but not
7 necessarily the genome itself.

8 Hemopet's proposed construction, by contrast, accurately reflects that these
9 terms can, but are not necessarily required to, include many types of data regarding
10 the genotypic profile of an animal, including those categories of data mentioned in
11 Hill's construction.

12 Support for Hemopet's proposed construction can be traced back to Hemopet
13 patents preceding the '343. For example, the '343 is a divisional of U.S. 6,287,254
14 ("the '254," attached as Ex. 4), which bears the same inventor as the '343, is
15 incorporated by reference in the '343, and is cited in the prosecution history of the
16 '343.³ The '254 specification describes "genotypic information:"

17 The genotypic information relates to genetic mapping, genetic
18 background, and genetic screening databases. This includes data
19 obtained from the pedigree, family history, heritable physical
20 characteristics, genetic screening tests, DNA testing, genomic
21 mapping, and related laboratory assessment of the gene product for
22 known or suspected congenital and heritable traits. In this application,
23 the term "gene product" means the specific phenotypic
characteristic(s) resulting from the expression of the genotype, and
may include certain specific laboratory test data

24 Ex. 4 at 2:40–49; *see also* Ex. 5, '343 File History, at 886-887. The '254 likewise
25 describes genetic information as "derived from the canine genome project." Ex. 4 at
26

27 _____
28 ³ The '254 is not asserted in this litigation.

1 9:49–50. The '254 explicitly discloses that such genomic data differs from Hill's
 2 simple "data related to the entire DNA sequence of the organism:"

3 Recent advances in molecular genetics have focused on mapping the
 4 human genome, and this has stimulated interest in developing parallel
 5 genetic maps for animals. For example, it is estimated that a minimum
 6 of ten years and several million dollars will be needed to map the
 7 canine genome. Once developed, a genetic map provides information
 8 about the relative order and placement of genes or specific DNA
 9 markers on specific chromosomes. This allows one to locate specific
 10 regions on chromosomes where genes of interest are likely to be
 found. Once a molecular marker is identified close to a specific gene
 of interest, screening tests for this particular marker can be used to
 identify individuals carrying or expressing the trait.

11 *Id.* at 10:51–63. This portion of the intrinsic record demonstrates that "genomic
 12 data" may in fact include the data that Hill's hopes to exclude from the scope of the
 13 patents. Further, a person of ordinary skill in the art at the time would understand
 14 that by relying on this type of data, the patentee was relying on genomic
 15 technologies' ability to monitor the activity of multiple genes simultaneously at the
 16 DNA, RNA, and protein level. Dr. Sameer Al-Murrani, one of Hill's former
 17 research scientists, has stated as an example in his own patent application that
 18 "Goldstein does not describe a functional genomic profile as in the present
 19 invention. ... The functional genomic profile can be defined as a pattern of two or
 20 more polynucleotides (DNA or RNA), peptides, proteins, metabolites, biomarkers,
 21 SNPs or combinations thereof." Ex. 3, Al-Murrani, at 4677.⁴ *See also* Ex. 2 at 4
 22 ("Contrary to nutrigenetics, nutrigenomics analyzes the effects of nutrients on the
 23 genome, proteome, and metabolome.").

24 The claimed invention of the '343 contemplates the same type of genomic
 25 data. The '343 recognized that there was a need for a new bioinformatics system to
 26 integrate and analyze "genetic identifier, genomic mapping, and genetic assessment

27 ⁴Hill's is the current assignee of this patent.
 28

1 data.” ’343 at 1:34–39. According to the ’343 specification—the single best guide
 2 to the meaning of a claim term—this data includes a wide variety of genotypic
 3 profile data such as, for example, “DNA fingerprinting (the gene map)” data and
 4 data resulting from “restriction fragment length polymorphism (RFLP), polymerase
 5 chain reaction RFLP, sequence-specific oligonucleotide (SSO), and sequence-
 6 specific primer (SSP)” assays. ’343 at 4:48–64. This data also includes data
 7 regarding “genotypic descriptors” of various diagnostic tests for diseases and
 8 disorders. *See, e.g., id.* at 9:59–60, 10:7–8, 10:40–41, 11:40–41. For example, the
 9 specification describes DNA fingerprinting data for “Major histocompatibility
 10 complex (MHC) Class I and II alleles [analyses of HLA, DLA, or equivalent animal
 11 antigenic specificities];” and “genotyping; gene mapping and fingerprinting.” *Id.* at
 12 11:43–46. Likewise, the ’343 specification discloses the same type of genetic
 13 marker data described in the ’254. *Id.* at 18:24–30 (“Database 207 can be a genetic
 14 marker database...”). Further, the prosecution history of the ’343 not only cites the
 15 portion of the ’254 specification discussed above, but it explicitly states that “the
 16 genetic data base also includes data relating to gene expression.” Ex. 5 at 887.

17 The extrinsic evidence also heavily weighs in favor of Hemopet’s proposed
 18 construction. For example, Hill’s itself has previously described the field of the
 19 Hemopet patents-in-suit, “nutrigenomics,” as “analyzing the effects of nutrients on
 20 the genome, proteome, and metabolome.” Ex. 2 at 4. The publication adds:

21 [N]ew genomic technologies, the so-called ‘-omics tools,’ are now
 22 elucidating the basis of these associations. These technologies monitor
 23 the activity of multiple genes simultaneously at the level of RNA by
 24 transcriptomics, the level of proteins by proteomics, and ultimately the
 level of metabolites by metabolomics.

25 *Id.* at 1. Thus, according to Hill’s publication (and consistent with Hemopet’s
 26 proposed construction), “genomic data” includes RNA-, protein-, and metabolite-
 27

28

1 level data. Hill's proposed construction unjustifiably removes this type of
 2 information from the scope of the claim.

3 In a similar vein, a Hill's patent application, Ex. 3 at 4677, defined
 4 “functional genomic profile,” as “a pattern of two or more polynucleotides (DNA or
 5 RNA), peptides, proteins, metabolites, biomarkers, SNPs or combinations thereof.”
 6 *See also* Ex. 3 at 4688 (“The term ‘functional genomic profile’ herein refers to the
 7 whole or any part of the functional consequences of expression of gene sequences,
 8 including production and function of mRNA’s, proteins, and metabolites.”). This
 9 extrinsic evidence further undercuts Hill's attempt to exclude gene expression,
 10 protein expression, and similar forms of data from the scope of “genomic data.”

11 Hill's alleged support for its constructions is either not on point or
 12 undermines its definition. As intrinsic evidence, Hill's cites broad swaths of the
 13 patent prosecution history for each of the four Hemopet patents without any
 14 pincites whatsoever—stating only “*passim*”—making it virtually impossible to
 15 identify which aspects of these documents it is referencing.⁵ Hill's cites, for
 16 example, to “*passim*” within an Amendment After Final on October 27, 2010 filed
 17 by the patentee during prosecution of the ’343 Patent. But the remarks in this
 18 Amendment involve the same portions of the ’254 specification cited above. Ex. 4
 19 at 2:40–49. As discussed above, this intrinsic evidence undermines any suggestion
 20 by Hill's (assuming Hill's is in fact making such a suggestion) that the patentee
 21 made any relevant disclaimers during the prosecution because they show that
 22 “genomic data” includes “data obtained from mapping and related laboratory
 23 assessment of the gene product.” *Id.* “Absent a clear disavowal or contrary

24 ⁵ Patent Local Rules 4-2 and 4-3 require Hill's to “identify all references from the
 25 specification or prosecution history that support its proposed construction”
 26 Hill's citation to “*passim*” violates the spirit, if not the letter, of the Rules. Because
 27 of Hill's violation, Hemopet has been prejudiced in its ability to counter Hill's
 28 positions. Accordingly, Hill's arguments and evidence in response should be
 discounted.

1 definition in the specification or the prosecution history, the patentee is entitled to
 2 the full scope of its claim language.” *August Tech. Corp. v. Camtek, Ltd.*, 655 F.3d
 3 1278, 1286 (Fed. Cir. 2011) (citing *Home Diagnostics, Inc. v. LifeScan, Inc.*, 381
 4 F.3d 1352, 1358 (Fed. Cir. 2004)).

5 Hill’s extrinsic evidence fairs no better. For example, Hill’s cites to Cousins,
 6 but ignores that during the prosecution of the Hemopet patents, the patentee already
 7 distinguished from Cousins (to the PTO’s satisfaction):

8 What Cousins (1999) teaches is the effect of nutrient influences on
 9 gene expression. This is not genomic data or genomic map data.

10 Cousins recognizes the complexity of genomic organization (page
 11 573), and therefore from Cousin’s own words that is an admission that
 12 his disclosure is not accessing first comprising genomic map data
 13 relating to a physiological condition, and nor is it accessing second
 14 data comprising the effect of nutrition on the genomic map data
 relating to the physiological condition of an animal.

15 Ex. 6, ’099 File History, at 2593. The patentee distinguished Cousins’ single-gene
 16 expression, but never suggested that that a more comprehensive examination of
 17 gene expression derived from the genomic data fell outside the scope of the claims,
 18 which is the net effect of Hill’s construction. Moreover, Hill’s interpretation of this
 19 statement cannot be accurate because, as discussed above, the specification of the
 20 ’254 (incorporated into the asserted Hemopet patents-in-suit) states that “the term
 21 ‘gene product’ means the specific phenotypic characteristic(s) resulting from the
 22 expression of the genotype, and may include certain specific laboratory test data.”

23 Ex. 4 at 2:47–49. Similarly, the prosecution history of the ’343 explicitly states:
 24 “As indicated, the Applicant has established, by incorporation of the parent
 25 application, Application 09/432,581 that the genetic data base includes data relating
 26 to gene expression.” Ex. 5 at 887 (emphasis added).

1 Hill's other attempts to limit the scope of the claims using extrinsic evidence
2 similarly cannot withstand comparison to the intrinsic evidence—in particular, the
3 patentee's comments during prosecution affirmatively distinguishing Hill's
4 extrinsic evidence. For example, Hill's contends that the Wainfran reference limits
5 the claims, but the patentee's discussion of the Wainfran reference underscores the
6 stark difference between that reference and the claimed invention:

7 Wainfran is distinguishable fundamentally because the present claims
8 as amended relate to canine and feline, and gastrointestinal and
9 immunological function. Further the pending claims require the
10 analysis of the genomic data. . . . Contrarily, Wainfran is concerned
11 with inducing carcinogenic, a rat, and has nothing to do with genomic
12 data. Wainfran is concerned with experimental use of lipotrope- or
13 methyl- deficient diets causing DNA methylation, a feature of
14 epigenetics and cellular differentiation. This impacts the transcription
15 of genes rather than genomic expression per se. This is not after
16 accessing a genomic database of anything (not even the rat). Simply, a
specific dietary deprivation can cause cancer by methylating DNA.
There is no analysis of different data bases (nutritional or genomic).
Thus, Wainfran is far removed from the overall inventive conceptual
and specific features as claimed.

17 *Id.* at 888; *see also id.* (distinguishing Hill's cited Cunningham reference because it
18 “does not teach the effect of nutrition on the genomic data function in animals” or
19 “the effect of nutrition on the expression of a genetic descriptor of the genomic
20 data”).

21 Hill's also relies on several definitions of the word “genome” from
22 Chambers, McGraw-Hill, and Merriam-Webster's, Exs. 8, 9, and 10, but as
23 explained above, consistent with the specifications (and Hill's own publications)
24 “genomic data” is necessarily data about all or part the genome, but not the genome
25 itself.

26

27

28

1 In short, Hill's proposed construction only holds water if the Court ignores
 2 context, *i.e.*, the intrinsic evidence. The Court should decline Hill's invitation to
 3 adopt constructions plainly inconsistent with that evidence.

4 **2. “genomic map,” “genomic map data,” and “at least one gene
 5 from a genomic map”**

Claim Term (Claim)	Hemopet’s Proposed Construction	Defendant’s Proposed Construction
“genomic map” (’354 Patent, Claims 1, 2, 9, 10)	“the genotypic profile of an organism”	Indefinite. “The entire DNA sequence of an organism, not genetic information, genetic data, or gene expression data (<i>i.e.</i> , transcription, mRNA translation, posttranslational modification, and protein gene product data).”
“genomic map data” (’354 Patent Claims 1, 2, 9, 10) (’099 Patent, Claim 1)	“data regarding the genotypic profile of an organism having been derived from efforts to map its genetic material”	
“at least one gene from a genomic map” (’587 Patent, Claims 1, 8)	“at least one gene from the genotypic profile of an organism”	

18 The parties dispute (1) whether claim terms that use different words have
 19 different meanings, and (2) what type of data is included in “genomic map data.”
 20 Hill’s ignores the explicit differences between the claim terms and proposes an
 21 identical (and faulty) construction for each term. By contrast, Hemopet’s proposed
 22 constructions recognize the difference between a “genomic map,” “genomic map
 23 data,” and “at least one gene from a genomic map.” And like the terms in the
 24 previous section, Hemopet’s construction for “genomic map data” accurately
 25 reflects the various types of data contemplated by the ’354, ’587, and ’099 Patents.

26 Contrary to Hill’s constructions, these three terms have different meanings.
 27 Analogizing to a census helps elucidate the differences. A census is the catalogue of
 28

1 the number of residents in a particular country or state, their age, their race, address,
2 marital status, etc. Similarly, the “genomic map” is the catalogue of the genetic (or
3 genotypic) information of an organism, *i.e.*, location, sequence, expression level,
4 etc. This genomic catalogue includes known and unknown genes and gene
5 sequences at the DNA, RNA, and protein level. *See, e.g.*, ’354/’099 2:15–19; Ex. 2
6 at 2 (“The genome is an organism’s complete set of DNA”); Ex. 3 at 4688
7 (“The term ‘functional genomic profile’ herein refers to the whole or any part of the
8 functional consequences of expression of gene sequences, including production and
9 function of mRNA’s, proteins, and metabolites.”). Notably, the claims do not use
10 the simple term “genome” in isolation.

11 Additionally, much in the same way that “genomic data” is not limited to
12 “data related to the entire DNA sequence” as Hill’s suggests, the “genomic map” is
13 not simply “the entire DNA sequence,” *i.e.*, the entire “side-by-side arrangement of
14 nucleotide bases.” Ex. 2 at 2. No intrinsic or extrinsic evidence requires such a
15 narrow definition. To the contrary, the ’354 specification discloses genotyping,
16 gene mapping, and fingerprinting using restriction fragment length polymorphism,
17 sequence-specific oligonucleotides and primers, and polymerase chain reaction.
18 *See, e.g.*, ’354 at 4:53–64. These techniques involve deriving information about the
19 genomic map but do not implicate “the entire DNA sequence.”

20 For similar reasons, there is also a difference between “genomic data” and
21 “genomic map data.” Going back to the census analogy, the census is the catalog
22 of residents, while census data is particular data derived from the Census Bureau’s
23 efforts to create that catalogue – *i.e.*, the fact that California has a significantly
24 higher percentage of foreign-born persons than the United States average would be
25 “census data” but not the “census.” Similarly, genomic map data is particular data
26 derived from efforts to map or catalogue the genome. The ’354 and ’099 Patent
27 specifications support Hemopet’s construction of “genomic map data” just as they
28 support its constructions for “genomic map.” That is, “genomic map data” reflects

1 results of DNA fingerprinting, genotyping, and gene mapping, among other method
2 to map genetic material. *See, e.g., id.* at 11:43–46.

3 Finally, “at least one gene from a genomic map” is simply the plain and
4 ordinary meaning of “at least one gene from” (*i.e.*, one or more genes out of) the
5 genomic map, which as discussed above, includes known and unknown genes and
6 gene sequences at the DNA, RNA, and protein level. In other words, “at least one
7 gene from a genomic map” is one data point out of the total set of data points that
8 make up the whole—much like “at least one household from the census” would be
9 one data point out of the census.

10 Hill’s proposed construction makes no sense as to “genomic map” and “at
11 least one gene from a genomic map” because, as discussed above, these terms differ
12 from “genomic map data.¹” Hill’s proposed construction really only applies to
13 “genomic map data,” but, even then, its proposed construction suffers from the
14 same previously-discussed evidentiary shortcomings. That is, Hill’s attempt to
15 exclude data related to “transcription of genes, gene expression, genetic
16 information, genetic data, gene expression data, mRNA translation, post-
17 translational modification, or protein gene product data” cannot be reconciled with
18 the intrinsic and extrinsic evidence.

19 The ’354 and ’099 Patent specifications—which are nearly identical to each
20 other and to that of the ’343 Patent—repeatedly describe how the data contemplated
21 by the claimed inventions includes the gene expression and similar data that Hill’s
22 construction excludes from the scope of the claims. *See, e.g.,* ’354/’099 at 1:36–43,
23 2:11–33, 4:9–19, 4:48–64, 8:55–9:3, 11:33–37, 17:13–18 , 18:24–30, 11:32–37,
24 11:43–46; Ex. 4 at 2:40–49, 9:49–52. The extrinsic evidence likewise supports
25 Hemopet’s proposed construction of “genomic map data” and counsels against
26 Hill’s overly narrow interpretation. *See* Ex. 2 at 1, 4; Ex. 3 at 4677, 4688.

27 For these reasons, and the reasons discussed in the preceding section, the
28 Court should adopt Hemopet’s proposed constructions.

1 **3. “expression of the at least one gene includes genomic map**
 2 **data”**

3 Claim Term (Claim)	4 Hemopet’s Proposed Construction	5 Defendant’s Proposed Construction
6 “expression of the at least 7 one gene includes 8 genomic map data” 9 (’354 Patent, Claims 2 10 and 10)	11 “the level of gene product 12 of the at least one gene 13 includes genomic map 14 data”	15 Indefinite. 16 “The entire DNA 17 sequence of an organism, 18 not genetic information, 19 genetic data, or gene 20 expression data (i.e., 21 transcription, mRNA 22 translation, 23 posttranslational 24 modification, and protein 25 gene product data).”
26 “expression of at least one gene from a genomic 27 map” (’587 Patent, Claim 1, 8)	28 “the level of gene product 29 of at least one gene from a genomic map”	
30 “the expression of genes 31 in the genomic map data” 32 (’099 Patent, Claim 1)	33 “the levels of gene 34 products of the genes in 35 the genomic map data” ⁶	

1 The parties, of course, disagree on the meaning of “genomic map data” and
 2 “genomic map” as used in these terms. As discussed above, Hemopet’s
 3 constructions of “genomic map” and “genomic map data” are more accurate, better
 4 supported, and make more sense. The parties also dispute the meaning of
 5 “expression of at least one gene.” Hemopet’s proposed construction is derived from
 6 the language of the specification: “In this application, the term “gene product”
 7 means the specific phenotypic characteristic(s) resulting from the expression of the
 8 genotype, and may include certain specific laboratory test data.” ’354 at 23:48–51.

9 Hill’s proposes a construction that again simply lumps these terms together
 10 as identical to all of the other “genomics terms.” This leads to the nonsensical
 11 construction by Hill’s that the terms “expression of at least one gene from a genomic
 12 map” means the same thing as the term “at least one gene from a genomic

13 ⁶ Hill’s initial proposal of terms for construction did not include this term.

1 map” which both in turn mean the same thing as “[t]he entire DNA sequence of an
 2 organism . . .” Apparently, to Hill’s, the phrase “at least one” should be interpreted
 3 to mean “all” and the term “expression” should be given no meaning entirely. This
 4 interpretation has no support in the specifications let alone the English language
 5 and should be rejected.

6 C. “Analyzing...” Terms

7 Claim Term (Claim)	8 Hemopet’s Proposed Construction	9 Defendant’s Proposed Construction
10 “analyzing” ('343 Patent, Claim 1)	11 “examining”	12 Indefinite. <i>See proposed construction of “analyzing” in the term “analyzing by use of a computer, the first and second data” below.</i>
13 14 “analyzing by use of a 15 computer, the first and 16 second data” ('343 Patent, Claim 1)	17 “examining, with the assistance of a computer, the first and second data”	18 Indefinite. Plain and ordinary meaning.

19 Hemopet seeks construction of “analyzing” from claim 1 of the ’343. Hill’s
 20 seeks construction of “analyzing by use of a computer, the first and second data”
 21 from the same claim. While Hemopet does not think that construction of this
 22 additional term is necessary, it has proposed a construction of this term.

23 Hemopet’s constructions are supported by the specification and the
 24 applicable extrinsic evidence. The plain and ordinary meaning of the term
 25 “analyzing” is “examining,” which is consistent with the meaning afforded to the
 26 verb “analyze” by the Oxford American Dictionary of Current English from the
 27 year the parent application to the ’343 was filed. *See* Ex. 7 at 25 (1999) (defining
 28 “analyze” as “examine in detail the constitution or structure of”). The term

1 “analyzing by use of a computer, the first and second data” therefore means
 2 “examining, with the assistance of a computer, the first and second data.”

3 Hill’s offers no evidence, intrinsic or extrinsic, to suggest that the plain and
 4 ordinary meaning of these terms means anything other than what Hemopet has
 5 proposed. In fact, the only evidence Hill’s cites at all with respect to this term is the
 6 Final Office Action for U.S. Patent Application No. 13/106,714 from August 27,
 7 2012. But Hill’s offers no citation to any part of this document that would define
 8 these terms in any other meaningful way. Hill’s instead relies on its assertion that
 9 this term is indefinite. But as already discussed, Hill’s bears the burden of
 10 establishing indefiniteness by clear and convincing evidence—this barebones
 11 statement will not suffice. *Young*, 492 F.3d at 1345.

12 **D. “Relating...” Terms**

13 Claim Term (Claim)	14 Hemopet’s Proposed Construction	15 Defendant’s Proposed Construction
16 “relate/relating” 17 (’343 Patent, Claim 1); 18 (’354 Patent, Claim 1, 2, 10); (’099 Patent, Claim 1); (’587 Patent, Claim 1, 8)	19 “have/having a relationship with”	20 Indefinite. Plain and ordinary meaning.

21 Hill’s proposed construing the term “relate/relating” in several of the patents.
 22 Hemopet does not believe these terms need construction but have offered a
 23 proposed construction.

24 The term “relate” or “relating” in these claims describe the data obtained for
 25 an animal with a particular physical characteristic. The plain and ordinary meaning
 26 of the word “relate” is “to have a relationship with.” Hill’s offers no intrinsic or
 27 extrinsic evidence to the contrary, citing not a single dictionary definition or portion
 28 of the specification. Instead, as with the “analyzing” terms from above, Hill’s cites

1 only the Final Office Action for U.S. Patent Application No. 13/106,714 from
 2 August 27, 2012, without any citation to a specific sentence or even page of this
 3 document.

4 **E. “Formulating” and “Preparing” Terms**

Claim Term (Claim)	Hemopet’s Proposed Construction	Defendant’s Proposed Construction
7 “formulate/formulating 8 a nutritional diet 9 [product]” (‘343 Patent, 10 Claim 1); (‘354 Patent, Claims 1, 2, 9)	“[create/creating] a particular nutrient or caloric composition”	“develop[ing] a complete and final food formula/food product.”
11 “prepare/preparing a 12 nutritional diet 13 [product]” (‘343 Patent, 14 Claim 2); (‘354 Patent, Claims 1, 9, 10)	“[manufacture/manufacturing g] a particular nutrient or caloric	“make/making a complete and final food formula/food product”

15 Hill’s seeks construction of two terms relating to formulating and preparing a
 16 nutritional diet or diet product. Although Hemopet does not think that construction
 17 of these terms is necessary, Hemopet has proposed constructions.

18 The intrinsic evidence strongly supports Hemopet’s proposed constructions.
 19 The ’343, ’354, and ’099 specifications emphasize that the act of formulating or
 20 preparing is with reference to a nutritional diet or diet product, which involves only
 21 creating or manufacturing a product with a particular nutrient or caloric
 22 composition. *See* ’343 at 13:9–11 (“The nutritional regimen is at least related to the
 23 nutrient or caloric composition needed for the dog subject”); ’354/’099 at
 24 13:9–11 (same); ’587 at 13:9–11 (same). The specification teaches the use of
 25 additives, supplements, or nutraceuticals—anything related to the general “design
 26 of nutritional requirements or therapeutic and maintenance interventions.” ’343 at

1 13:29–20; *see also* '354 at 24:5–7 (“The information is also used to design disease
2 prevention programs based on dietary/environmental modification . . .”).

3 Additionally, the specification makes clear that formulating and preparing
4 can include modifying a pre-existing food or supplement. The specification
5 discloses that “for instance the food supplements, nutraceuticals and the like, can be
6 modified by additions and/or subtractions of components based on the determined
7 relationship” with the other relevant data. '343 at 13:31–34; '354/'099 at 13:31–34
8 (same).

9 By contrast, Hill’s proposed construction (again) improperly imports
10 extraneous limitations into the claims by requiring a “final” food formula or
11 product. Hill’s offers nothing from the specification to support this limitation, and
12 the only evidence offered by Hill’s are various dictionary definitions of “formulate”
13 and “prepare.” None of the dictionary definitions offered by Hill’s, however,
14 require that the formulation or preparation of a nutritional diet or diet product
15 involve something that is “final” or even a “formula.” Chambers, for example,
16 defines “prepare” as “to make or get ready,” or, consistent with Hemopet’s
17 construction, as “to make, produce, mix or compound (*e.g.* a chemical) by some
18 process.” Ex. 8 at 1296. The American Heritage Dictionary defines “prepare” as “to
19 put together or make by combining various elements or ingredients.” No reference
20 is made to a “final” determination or to the use of a “formula.” Ex. 11 at 664.
21 Chambers even defines “formulate” as either “to reduce to or express in a formula”
22 or “to state or express in a clear or definite form.” Ex. 8 at 630. Again, no reference
23 is made to a “final” determination, which is consistent with the specification’s
24 teachings that the “determinations” be predictive of “nutritional requirements,”
25 among others. *See, e.g.*, '343 at 13:19–21.

26 In *Phillips*, the Federal Circuit warned that dictionaries and other extrinsic
27 evidence “may be useful to the court, but it is unlikely to result in a reliable
28 interpretation of patent claim scope unless considered in the context of the intrinsic

evidence.” 415 F.3d at 1319. Here, the specification describes a “regimen” related to “the nutrient or caloric composition needed,” *see, e.g.*, ’343 at 13:9–11, which teaches only identification of certain nutrient or caloric compositions and not the identification of a “final food formula,” as Hill’s suggests. *See also* ’587 at 13:64–67 (“The determination of the health care, well-being, nutritional or other therapeutic requirements and suggestions for promoting and maintaining health of the dog is reported on a communications network including the Internet.”). The clear object of the formulating and preparing verbs in the claims is explicitly a “nutritional diet” or “nutritional diet product,” and there is no basis to read in any limitation that the diet or diet product consist of “final food formula.” Because nothing in the specification or any other portion of the intrinsic record requires this additional limitation imposed by Hill’s, the Court should reject its flawed construction

F. “Determining...” Terms

Claim Term (Claim)	Hemopet’s Proposed Construction	Defendant’s Proposed Construction
“determining” ('354 Patent, Claims 1, 2, 9, 10) ('587 Patent, Claims 1, 8) ('099 Patent, Claims 1)	“identifying or establishing”	Indefinite. Plain and ordinary meaning.
“[determine/determining] a relationship between [said/the] first and second data [using a suitably programmed computer]” ('354 Patent, Claims 1, 2, 9, 10), ('099 Patent, Claim 1), ('587 Patent, Claims 1, 8)	“[identify/identifying or establish/establishing] a relationship between [said/the] first and second data [with the assistance of a suitably programmed computer]”	Indefinite. Plain and ordinary meaning.
“determining a nutritional	“identifying or	“Developing a complete

1	diet" ('587 Patent, Claims	establishing a particular	and final food
2	1, 8)	nutrient or caloric	formula/food product."
3		composition" ⁷	

4 Hemopet seeks construction of "determining" from the asserted claims of the
 5 '354, '587, and '099 Patents. Hill's seeks construction of "[determine/ determining]
 6 a relationship between [said/the] first and second data" from the same claims and
 7 "determining a nutritional diet" from claims 1 and 8 of the '587 Patent. While
 8 Hemopet does not think that construction of these additional terms is necessary, it
 9 has proposed constructions consistent with its proposed construction of
 10 "determining."

11 According to the 1999 edition of the Oxford American Dictionary of Current
 12 English, "determine" means "to find out or establish precisely." Ex. 7 at 212.
 13 Neither the claim language nor the specification curtails the scope of "determine"
 14 from this ordinary meaning. Hemopet's proposed construction of "[determine/
 15 determining] a relationship between [said/the] first and second data" applies this
 16 ordinary meaning to the balance of the claim language.

17 Hill's proposed construction should be rejected for the same reasons as Hill's
 18 "formulating" and "preparing" constructions. *See supra* Part IV.E. Hill's again
 19 attempts to import limitations from the specification (i.e., "final food formula") and
 20 render remaining claim language superfluous. *Id.* Either of these reasons provides
 21 independent and sufficient grounds to reject Hill's erroneous proposed construction,
 22 and adopt Hemopet's simpler and more accurate construction. The only reference in
 23 the various definitions of the word "determine" offered by Hill's to something
 24 "final" is the alternative definition in the Webster's II New Collection relating to

25
 26 ⁷ Defendant initially proposed construction of the term "determining." After the
 27 parties exchanged term proposals, Defendant instead offered a construction of the
 28 term "determining a nutritional diet." Should the Court construe this term, Hemopet
 offers this construction consistent with its other terms.

1 “end[ing] or decid[ing] by final, esp. judicial, action.” Ex. 10 at 309. The better
2 definition is the one offered by Hemopet from the Oxford American Dictionary of
3 Current English, Ex. 7 at 212 (1999), which defines “determine” as “to find out or
4 establish precisely,” and is in fact consistent with many of the alternative
5 definitions in the dictionaries cited by Hill’s. *See, e.g.*, Chambers, Ex. 8 at 440,
6 (defining “determine” as “to put terms or bounds to; to limit; to fix or settle; to
7 define; to decide; to resolve; to cause to resolve; to put an end to (*law*).”).

8 **V. CONCLUSION**

9 For the foregoing reasons, the Court should adopt Hemopet’s claim
10 constructions and reject Hill’s constructions.

11
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